

## ARGUMENTS

The basis for the amendment can be found in the Specification on page 7, lines 2 - 7, as well as, page 8, lines 5 - 7.

### I.

Previously drafted, Claim 1, identifies those Vitamin C metabolites known to treat cancer cells. However, the Specification unequivocally identifies Vitamin C metabolites as a discrete group of compounds.

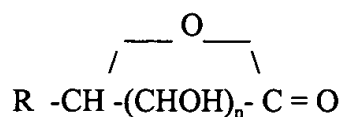
In particular, page 7 of the Specification specifically identifies the group of Vitamin C metabolites as being, "selected from the group consisting of aldonic acids, the aldono-lactones, aldono-lactides and non-toxic metal salts of aldonic acids, dehydroascorbic acid, threose, erythreose, 4-hydroxy-5-methyl-3(2H)-furanone, 3-hydroxykojic acid and 5-hydroxymaltol."

Further clarification of the group comprising Vitamin C metabolites can be found on Page 8 of the Specification, wherein three (3) United States Patents are incorporated into the present disclosure. Each of the incorporated Patents reiterate a clear definition of the chemical group, Vitamin C metabolites, and are provided herein verbatim:

The first incorporated patent, United States Patent 4,822,816, describes Vitamin C

metabolites as, "The metabolites of ascorbic acid and its derivatives include the aldo-lactones and edible salts of aldonic acids" (Column 2, lines 17 - 19).

The second and third patents, United States Patent 4,968,716 and 5,070,085, each contain, "The metabolites of ascorbic acid and its derivatives include the aldonic acids, aldono-lactones, aldono-lactides and edible salts of aldonic acids. As will appear, the compositions of the present invention are characterized by the presence of at least one or more of these metabolites corresponding to three specific aldonic acids: L-threonic acid, L-xylonic acid and L-lyxonic acid. The aldono-lactones have the structural formula:



wherein R is hydrogen or -CH<sub>2</sub>-OH and n=1 to 3." (Column 3, lines 13 - 27; and Column 3, lines 7 - 20, respectively)<sup>1</sup>.

The Applicant asserts that there can be no doubt with regards to what compounds are members of the class called, "Vitamin C metabolites." The Specifications of the disclosed invention and two incorporated United States Patent, it appears, leave no room for doubt by either ambiguity or vagueness.

Therefore, having clearly identified the discreet group of chemicals being Vitamin C

---

<sup>1</sup> United States Patent Number 5,070,085 contains a typographical error in the aldono-lactone formula (Column 3, line 20), wherein the subscript 2 should follow the R-CH bond. One skilled in the art would be aware of the existence of the typographical error simply by observing the missing hydrogen on a -CH group.

metabolites in the Specification, the Applicant respectfully urges that the invention embraces Vitamin C metabolites.

Claim 1, as it is amended, now provides the proper structure of an independent Claim, for which, the particular Vitamin C metabolites, as previously disclosed, may properly be dependently claimed.

## II.

Lastly, the Applicant urges that the various Vitamin C metabolites cannot have acquired separate status in the art of treating because each is similar in form and function. That is, each is a physical breakdown of ascorbic acid (Vitamin C) and are being used to kill cancer cells. Therefore, a search of the prior art pertaining to cancer chemotherapeutic drugs should encompass all previously known compounds, including Vitamin C metabolites, for treating cancer cells.

The claims in this case are believed to be in condition for allowance.

## ELECTION

As explained above, the amendment of Claim 1 is believed to overcome the Examiner's requirement for an election of Vitamin C metabolite sub-species for examination. However, Applicant understands that in accordance with M.P.E.P. 818.03(b), an election still must be made with traverse.

Accordingly, if the Examiner does not agree with Applicant's sincere assertions that a restriction is not now required, Applicant elects to prosecute Claims 1 - 2 directed to the application of a single enhanced combination of one plasma-soluble metal salt of ascorbic acid with one or more nontoxic metal salts of aldonic acid.

Therefore, having elected a single species of Vitamin C metabolite, a nontoxic metal salt of aldonic acid, an election has been made in compliance with the Examiner's Office Action and M.P.E.P. 818.03(b).

### **CONCLUSION**

The Examiner's attention to this application is greatly appreciated.

The Applicant sincerely desires to speak with the Examiner concerning the matters discussed herein. To facilitate the opportunity to have a discussion, a copy of this Response was faxed, ATTN. Examiner J.D. Goldberg, to (703) 308-4556, on December 21, 2001.

If there is no objection, the Applicant will plan on calling the Examiner in the third or fourth week of January. Alternatively, if an appointment can be made, it is respectfully requested that a telephone call be placed to the undersigned to arrange for an appointment.

Respectfully submitted,

DRUMMOND & DUCKWORTH

A handwritten signature in black ink, appearing to read 'W.D.', with a long horizontal flourish extending to the right.

William Drummond

Registration No. 20,590

Attorneys for Applicant

Telephone: (949) 724-1255

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Serial No: 09/830,912

**AMENDMENT OF THE CLAIMS**

Please amend Claim 1:

1. A selective chemotherapy method which includes the step of contacting tumor cells with a composition comprising:

*No Subject  
Amount*

- (a) a plasma-soluble metal salt of ascorbic acid; and
- (b) one or more vitamin C metabolites [selected from the group consisting of
  - (i) aldonic acids, and the aldono-lactones, aldono-lactides and non-toxic metal salts thereof, and
  - (ii) dehydroascorbic acid, threose, erythreose, 4-hydroxy-5-methyl-3(2H)-furanone, 3-hydroxykojic acid and 5-hydroxymaltol].

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Serial No: 09/830,912

Please add Claims 3 - 14:

3. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is an aldonic acid.

✓ 4. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is a non-toxic metal salts of an aldonic acid.

5. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is an aldono-lactone.

6. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is a non-toxic metal salts of an aldono-lactone.

7. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is an aldono-lactide.

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Serial No: 09/830,912

8. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is a non-toxic metal salts of an aldono-lactide.

9. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is dehydroascorbic acid.

10. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is threose.

11. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is erythreose.

12. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is 4-hydroxy-5-methyl-3(2H)-furanone.

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Serial No: 09/830,912

13. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is 3-hydroxykojic acid.

14. The selective chemotherapy method of Claim 1 wherein said vitamin C metabolite is 5-hydroxymaltol.

### **REQUEST FOR RECONSIDERATION**

Because Applicant seeks protection for a medically important improvement for treating cancer, the Examiner is respectfully requested to reconsider the requirement of an election set forth in the Office Action of July 30, 2001, in light of the foregoing, and issue a Notice of Allowance.

As requested herein, the Applicant sincerely desires to speak with the Examiner concerning the foregoing at the Examiner's convenience.

Respectfully submitted,

DRUMMOND & DUCKWORTH

A handwritten signature in black ink, appearing to read 'W. H. Drummond', followed by a horizontal line and a small flourish.

William H. Drummond  
Registration No. 20,590  
Attorney for Applicant  
Telephone: (949) 724-1255